## Amendment

## In the Claims

- (currently amended) A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:
- (a) a therapeutically effective amount of at least one <u>herbal active</u> agent selected from the group of herbal and homeopathic active agents and drugs;

wherein the herbal and homeopathic agents are active agent is selected from the group consisting of bioactive herbs, herbal extracts, tinetures, essential oils, and mixtures thereof, and

the drugs are selected from the group consisting of analgesies, antiinflammatories, antihistamines, antigens, steroids other than anti-inflammatories, vitamins, enzymes, antipyreties, antimalarial drugs, antiuleer drugs, peptides, and combinations thereof: and

- (b) a pharmaceutically acceptable solid bioadhesive carrier, comprising a mucoadhesive synthetic polycarboxylic acid polymer, in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.
- (previously presented) The solid composition of claim 1 wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes
- 3. (previously presented) The solid composition of claim 1 where the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

45069446 - 2 - EBL 102

U.S.S.N. 10/083,413 Filed; February 27, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.116

4. (previously presented) The composition of claim 1 wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof.

5. (canceled)

6. (currently amended) The composition of claim 1 wherein the herbal and

homeopathic agents are active agent is selected from the group consisting of Echinacea,

Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, menthol, Plantago, Baptisia,

Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed

extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Kramerica, Matricaria,

Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family

Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal

infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower

extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria

root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof.

7. (previously presented) The composition of claim 1, wherein the herbal active

agent is an essential oil selected from the group consisting of citronella oil, lemon oil,

citron oil, pomelo peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus

officinalis oil, cinnamon oil, cajeput oil, eucalyptus oil, fennel oil, geranium oil, girofle

oil, lavendar oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil,

sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

45069446 - 3 - EBL 102

8. (previously presented) The composition of claim 7, wherein the herbal active

agent is an essential oil selected from the group consisting of cinnamon oil, tea-tree oil,

citronella oil, and combinations thereof.

9. (previously presented) The composition of claim 6, wherein the herbal active

agent comprises at least one monoterpene with three unsaturations,

10. (previously presented) The composition of claim 1, wherein the herbal active

agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of

limonene and at least one myrcene, a-pinene, b-pinene, and sabinene characterized in that

at least 60% by weight of the mixture is limonene.

11. (previously presented) The composition of claim 9, wherein the monoterpene

with three unsaturations is a citrus oil selected from the group consisting of lemon oil,

pomelo oil, citron oil, and combinations thereof.

12. (previously presented) The composition of claim 1, further comprising a salt

selected from the group consisting of MgBr2, NaCl, KCl and mixtures thereof.

13. (canceled)

14. (previously presented) The composition of claim 1 further comprising

Carnallite or a salt of Carnallite.

15. (currently amended) The composition of claim 1, further comprising a non-

herbal active agent selected from the group consisting of anesthetics, analgesics, anti-

inflammatories, antihistamines, antigens, steroids other than anti-inflammatories,

vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides, and

combinations thereof.

45069446 - 4 -

EBL 102

## AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.116

16. (currently amended) The composition of claim 15, wherein the <u>non-herbal</u>

<u>active</u> agent is selected from the group consisting of at least one base or acid-addition salt
of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine,
chloroprocaine, tetracaine, bupivacaine, and etidocaine.

- 17. (previously presented) The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.
  - 18. (canceled)
- 19. (previously presented) The composition of claim 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.
- (previously presented) The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1.
- 21. (previously presented) The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivecaine.
- 22. (currently amended) The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of a mixture of crosslinked synthetic polycarboxylic acid polymers and mixtures thereof.

45069446 - 5 - EBL 102

U.S.S.N. 10/083,413 Filed; February 27, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION UNDER 37 C.F.R. § 1.116

23. (currently amended) The composition of claim 1 wherein the polymer is a

copolymer of one or more polymers selected from the group consisting of hydroxypropyl

cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl

cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch

derivatives, acrylic acid polymers, polymer of acrylic acid esters, polymers of vinyl

alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations

thereof.

24. (previously presented) The composition of claim 1 further comprising an

excipient selected from the group consisting of fillers, tableting excipients, lubricants,

 $enhancers,\,flavors,\,taste-masking\,\,agents,\,pH\,\,controlling\,\,compounds,\,dyes,\,stabilizers,\\$ 

enzyme inhibitors, and mixtures thereof.

25. (previously presented) The composition of claim 24 wherein the enhancers

are selected from the group consisting of bile acids and limonene.

26. (previously presented) The composition of claim 22 wherein the solid

bioadhesive carrier is selected from polyacrylic acid polymers crosslinked with a polymer

selected from the group consisting of polyalkenyl polyether, carboxymethylceullose,

hydroxymethylcellulose, and mixtures thereof.

Claims 27-37. (canceled)

38. (previously presented) The composition of claim 1, wherein the composition

has a surface area ranging from about 0.4 to about 3 cm<sup>2</sup>.

45069446 - 6 - EBL 102